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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,246	11/24/2003	James Say	TS-02-18	6045
30349	7590	12/28/2005	EXAMINER	
JACKSON & CO., LLP 6114 LA SALLE AVENUE SUITE 507 OAKLAND, CA 94611-2802			NATNITHITHADHA, NAVIN	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 12/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/722,246

Applicant(s)

SAY ET AL.

Examiner

Navin Natnithithadha

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-10 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

1. Claims 1, 11, and 22 have been amended. Claims 1-30 are pending.

### ***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-10, drawn to an insertion kit, classified in class 600, subclass 365.
  - II. Claims 11-30, drawn to a sensor control system and method, classified in class 600, subclass 345.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group I and Group II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention Group I has separate utility such as a biosensor insertion device. See MPEP § 806.05(d).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

During a telephone conversation with Seong-Kun Oh on 21 December 2005 a provisional election was made without traverse to prosecute the invention of Group II, claims 11-30. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-10 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 11-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In regard to specifically claims 11 and 14, the subject matter pertaining to a transmitter unit "attachable to the mounting unit" (see claim 11) or is "removably

attached to the mounting unit" (see claim 14) is not supported in the specification. The Specification, on page 61, lines 13-20, discloses the "on-skin sensor control unit 44 may optionally contain a transmitter 98." This is not a disclosure for having a transmitter "attachable" or "removably attached" to the mounting unit. Moreover, the Applicant has not disclosed that a transmitter unit attachable/removably attached to the mounting unit provides an advantage, is used for a particular purpose, or solves a stated problem.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 11-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Gross et al, US 6,275,717 B1 (hereinafter referred to as Gross).

Claim 11-30: Gross teaches a sensor control system (see fig. 1A), comprising: an electrochemical analyte sensor (electrodes 15, 16, 17 and voltage controller 19); a mounting unit 13, which is removable from the skin; and a transmitter unit 23 attachable/removably attached/operatively coupled to the mounting unit 13 for wirelessly transmitting data to a receiver 24 (see fig. 1A and 1B); an adhesive layer

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16/17. As to the method claims 23-30, Gross teaches a method of using the sensor control system in Figure 1A.

5. Claims 24-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Ward et al, US 5,800,420 A (hereinafter referred to as Gross '420).

Claim 24-30: Gross '420 teaches a method, comprising: transcutaneously positioning an electrochemical analyte sensor in a patient (using a sensor working electrode needle 55) (see fig. 8); adhesively attaching and removing a mounting unit (first part of housing 51) 52 (see col. 17, lines 66-67); and operatively coupling a transmitter unit 53 (misabeled as 52, second part of housing 51)) to mounting unit 52 so that the transmitter unit is configured for electrical communication (using contacts 64/65) with the sensor (see fig. 8). The second part 53 of housing 51 can be defined as a transmitter unit because microprocessor 59 communicates with a LCD 61 and/or can transmit audible signals through audible alarm 60.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 11-23 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 10/420,057 in view of Gross. Although the copending Application does not claim an attachable/removably attached transmitter, Gross teaches the transmitter unit (23) as claimed. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Applicants' claimed invention with Gross's transmitter unit (23) in order to have a disposable mounting unit (13) to prevent cross-contamination between users.

This is a provisional obviousness-type double patenting rejection.

7. Claims 11-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,175,752 B1 in view of Gross. Although Applicants' prior patent does not claim an attachable/removably attached transmitter, Gross teaches the transmitter unit (23) as claimed. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Applicants' claimed invention with Gross's transmitter unit (23) in order to have a disposable mounting unit (13) to prevent cross-contamination between users.

### ***Conclusion***

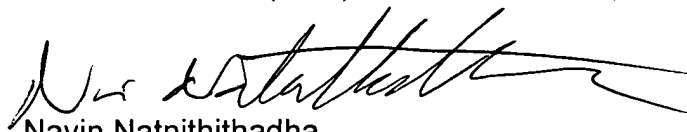
8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6,248,067 B1, US 6,254,586 B1, US 5,951,521 A, US 5,571,861 A, and US 5,390,671 A are pertinent to the subject matter of the Applicant's claims. The Examiner suggests reviewing these patents in responding to this Office Action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (571) 272-4732. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Navin Natnithithadha  
Patent Examiner  
GAU 3736  
22 December 2005